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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,041	06/22/2001	Tai-He Xia	41491	5481

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EXAMINER	
BRANNOCK, MICHAEL T	

ART UNIT	PAPER NUMBER
1646	16

DATE MAILED: 10/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/886,041	XIA ET AL.	
	Examiner	Art Unit	
	Michael Brannock	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *30 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *9,10 and 18-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-8 and 11-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Application: Claims and Amendments

Applicant is notified that the amendments put forth in Paper 15, 7/21/03, have been entered in full.

Response to Amendment

Applicant is notified that any remaining rejection, or grounds of rejection, that is not expressly maintained in this Office action has been withdrawn due to Applicant's amendments.

Maintained Rejections:

Claims 1-8, 11-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as set forth below.

Claim 1 requires "a variant of GAVE3". The word "variant" renders the claim indefinite because is a relative term, and the specification does not set forth the degree of variation allowed, nor how the degree is to be measured; thus, the metes and bounds of the claim cannot be determined.

Applicant argues that the word variant is adequately qualified by the limitation that the variant have GAVE3 function. This argument has been fully considered but not deemed persuasive. The specification does not describe any particular function that gave GAVE3 has, e.g. at pages 8-9, GAVE3 activity is described in a general and tautologous way wherein no particular meaning of the phrase GAVE3 function can be found. Thus, the presence of the

phrase "GAVE3 function" also renders the claim indefinite because it is unclear what this phrase is meant to encompass.

Claim 6 requires a "conservative amino acid substitution". This phrase renders the claim indefinite because the specification does not set forth which substitutions are deemed to be conservative and nor is there an art-recognized and agreed upon standard by which the artisan would reasonably know whether a particular substitution was within the bounds of the claim.

Applicant argues that the specification defines conservative substitutions at pages 14-15. This argument has been fully considered but not deemed persuasive for several reasons. The specification asserts that residues having "similar" side chains are conservative, yet the specification does set forth the groups that are considered similar. For, example the specification states that uncharged polar side chains are similar and make up a conservative group which is distinct form the group comprising non-polar side chains. Yet, the specification also puts forth beta-branched side chains form a group of similar amino acids. Thus, the specification first indicates that threonine and valine are not similar and then indicates that they are, see lines 25-28. The specification does not define conservative substitutions such that the artisan could know whether or not a particular substitution was conservative.

Note: Claim 7 has been amended to require that the nucleic acids hybridize but does not put forth any conditions under which the hybridization must occur. Therefore, the claim must be read as to include all possible hybridization conditions, and is thus no longer indefinite in this regard.

Claims 1, 3-8 and 11-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polynucleotides that encode a polypeptide of SEQ ID NO: 2 or fragments of a polypeptide of SEQ ID NO: 2, does not reasonably provide enablement for polynucleotides that do not encode a polypeptide or fragment of SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, as set forth previously.

Applicant argues that the artisan would clearly know how to ascertain whether a variant has a GAVE3 function. This argument has been fully considered but not deemed persuasive for two reasons. First, as indicated above, the specification does not set forth what particularly is a GAVE3 function. Second, as set forth previously, the issue here is that the specification has not provided guidance as to what properties of the allelic variants or sequence variants of the protein corresponding to SEQ ID NO: 2 might be desired nor any guidance as to which amino acid substitutions, deletions or insertions to make to achieve any desired property. Applicant has not defined a difference in structure or difference in function between the protein corresponding to SEQ ID NO: 2 and variants of said protein. If a variant of the protein corresponding to SEQ ID NO: 2 is to have a structure and function similar to the protein corresponding to SEQ ID NO: 2, then the specification has failed to teach one of skill in the art which amino acid substitutions, deletions or insertions to make that will preserve the structure and function of the protein corresponding to SEQ ID NO: 2. Conversely, if a protein variant of SEQ ID NO: 2 need not have a disclosed property, the specification has failed to teach how to use such a variant.

Applicant asserts that an artisan surveying a population can readily identify an allelic variant. This argument has been fully considered but not deemed persuasive. The artisan would certainly be able to identify an allelic variant were he or she been given one. The issue here is that the specification has simply provided the invitation to randomly try to find one, such random trial and error experimentation is undue.

Applicant argues that the examiner thought that it is unpredictable as to what portions of a molecule may be antigenic. This argument has been fully considered but not deemed persuasive. Applicant misunderstands the examiner's discussion. The examiner was referring to the fact that it is unpredictable what the effect of amino acid substitution will have on the antigenicity of the protein – the word "antigenicity" encompassing not only the ability of that protein to elicit an immune response but also the specificity of the antibodies produced. Thus the specification has failed to teach which residues can be substituted and still retain the antigenic characteristics of the parent protein.

Claims 1, 3-8 and 11-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as set forth previously.

The specification discloses a polynucleotide of SEQ ID NO: 1, yet the claims encompass polynucleotides not described in the specification, i.e. polynucleotides which comprise only portions of SEQ ID NO: 1, e.g. sequences from other species, mutated sequences, allelic

variants, or sequences that have a recited degree of identity. None of these sequences meet the written description provision of 35 U.S.C. 112, first paragraph.

Applicant argues the scope of the invention has been clearly described, particularly with regard to a specific function of the claimed polynucleotides. This argument has been fully considered but not deemed persuasive. As set forth above, the specification does not set forth a clear function for GAVE3.

Claims 1, 2, 7, 8 and 11-17 are rejected under 35 U.S.C. 102(a) as being anticipated by WO/01/036473, published 25 May 2001, as set forth previously.

WO/01/036473 disclose an isolated nucleic acid 100% identical to the instant SEQ ID NO: 1, see attached alignment, vectors, host cells, and methods of producing the encoded polypeptide, see the abstract.

Applicant argues that the rejection is improper because the prior art is not enabled. This argument has been fully considered but not deemed persuasive. Applicant has presented no reasons as to why this is so.

Claims 1, 3, 5-7, 11-17 are rejected under 35 U.S.C. 102(b) as being anticipated by WO98/56820, published 12/17/1998.

WO98/56820 disclose an isolated nucleic acid encoding a variant of SEQ ID NO: 2, see attached sequence alignment. Wherein said variant contains at least one functionally equivalent amino acid residue substitution, e.g. the variant disclosed by WO98/56820 is a G-protein coupled receptor, as is the instant SEQ ID NO: 2, thus the mutations are functionally equivalent in that

both receptors retain G-protein binding activity. Vectors, host cells, and methods of producing the encoded polypeptide are also disclosed, e.g. page 7.

Applicant argues that the claims require molecules with GAVE3 function, thus the cited reference does not teach the claimed invention. This argument has been fully considered but not deemed persuasive. As set forth above, the specification does not adequately define GAVE3 function. Thus, given the broadest reasonable interpretation of the claims, the GPCR taught by WO98/56820 and GAVE3 both share a GPCR function.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Please note the new official fax number below:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Thursdays from 8:00 a.m. to 5:30 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

October 9, 2003

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600